

SEP 28 2005

K051940

510(k) Summary for the CM 3910 Rotating Double Scheimpflug Camera

Name and Address of Sponsor

SIS Surgical Instrument Systems Ltd.
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Name and Address of Manufacturer

SIS Surgical Instrument Systems Ltd.
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Name and Address of Official Correspondent

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Device Name

Device trade name: CM 3910 Rotating Double Scheimpflug Camera
Classification name: Anterior segment analysis device
Common name: AC-powered slitlamp biomicroscope

Classification, Panel and Product Code

Device Classification: Class II, MXK
Reviewing Panel: Ophthalmic Devices

Indications for Use

The CM3910 is a device intended to take images of the anterior segment of the eye which includes the cornea, iris, pupil, anterior chamber and lens, to evaluate and analyse

- Corneal shape
- Lens shape
- Pachymetry (thickness of the cornea)
- Pupil size
- Lens thickness
- Condition of the lens
 - Location of cataracts (nuclear, subcapsular and or cortical), using Scheimpflug slit imaging with densitometry
 - State of the lens (opaque crystalline lens)
- Condition and position of implants (e.g. IOLs, phakic IOLs, intracorneal rings)
- Anterior chamber (size, volume and angle)
- Scheimpflug Image
- Position of the cornea relative to iris and lens

Predicate Devices

The Pentacam Scheimpflug Camera is claimed to be substantially equivalent to the following legally marketed devices:

- Pentacam Scheimpflug Camera of OCULUS Optikgeräte GmbH
- Orbscan IITM Keratometer manufactured by Orbtex, Inc.

Device Description

The CM 3910 Double-Scheimpflug Camera is a non-invasive, diagnostic system designed for the analysis of the anterior eye segment by means of Scheimpflug and Placido images. The Scheimpflug images are based on the Scheimpflug Principle for Slit Image photography. The system is table mounted and AC powered. The device consists of a measurement unit and a control unit with a CPU. The measuring system uses blue light (UV-free) given to a slit to illuminate the eye, and a CCD-Camera for taking images. The measuring unit takes pictures by a rotating scan of the anterior eye segment. It also includes a top view for eye tracking means and Placido imaging in the near infrared. From the acquired pictures, the control unit calculates a 3D-model and the topography of the eye.

All light sources used (Slit lamp, Placido Disc illumination, Top view illumination) are Light Emitting Diodes (LED) which produce little heat. Excess heat is conducted by appropriate metallic heat sinks. The encapsulation of the light sources consists of non-flammable materials (metals, glass). The device does not contain any incandescent lamp.

Product Comparison

| Characteristics | CM 3910 | Pentacam Scheimpflug Camera (Predicate) | Orbscan II™ Keratometer (Predicate) |
|---------------------------|--------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|
| References | | 510(k): K013941 | 510(k): K984443 |
| Intended use | Taking photos of the anterior segment of the eye which includes the cornea, pupil, anterior chamber and lens of the eye. | Taking photos of the anterior segment of the eye which includes the cornea, pupil, anterior chamber and lens of the eye. | Scan, map and display the geometry of the anterior segment of the eye. |
| Measuring Principle | Rotational scan of Double-Scheimpflug slit images merged with Placido Disc images. | Rotational scan of Scheimpflug slit images. | Parallel scanned slit images and Placido Disc images |
| Optical | Three Apertures | Single Aperture | Single Aperture |
| Viewing Means | LCD on Measurement Unit, 17" monitor on table | 15" Coloured Screen | 15" Coloured Screen |
| Observation Illumination | Infrared LED 810nm | Infrared LED 800nm | |
| Flash Output Illumination | Blue LED Light (UV-free) 470 nm, max. 15 mWsec | Blue LED Light (UV-free) 475nm, max. 2.5 Wsec | White flash light |
| Photography Camera | CCD Camera | CCD Camera | CCD Camera |
| Display | Data digital, displayed on a CPU | Data digital, displayed on a CPU | Data digital, displayed on a CPU |
| Image Resolution | 1004 x 1004 pixels | 800 x 600 pixels | 0.25 diopters |
| Image Size | 7.4 x 7.4 mm | 5.6 x 4.5 mm | |
| Photographic Range | Eligible 0 to 180° | Eligible 0 to 180° | Parallel scan |
| Photographic Series | 1 to 60 images | 1 to 50 photos | 2x 20 images from two sides |
| Slit Length | 15 mm | 14 mm | |
| Power Requirement | 110/220 VAC, 50/60 Hz | 110/220 VAC, 50/60 Hz | 110/220 VAC, 50/60 Hz 220/240 VAC, 50/60 Hz |
| Weight | 10 kg (Measurement Unit) | 9 kg | 15kg |

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Rationale for Substantial Equivalence

- The devices have the same intended use
- The devices utilize the same measuring principles (Slit Scan and Placido Disc)
- The devices utilize the same photographic medium (CCD Camera)
- The CM 3910 and one predicate device use light sources of comparable wavelength and intensity
- The devices use the same features like a
 - Head stabilizing device
 - Fixation target
 - Joy stick for measurement head adjustment
- All devices are considered “non invasive” as defined in 21 CFR §812.3(k)

Safety

The CM 3910 is a non-invasive diagnostic system, which contacts the patient only on his/her chin and forehead. The CM 3910 does not present or pose any new or additional risks for the prescribed intended uses. The light output is of an eye safe intensity and wavelength. The electrical safety requirements for medical devices are met. The CM 3910 is proven effective for its intended uses through internal performance tests.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Surgical Instrument Systems
c/o Kevin Walls, RAC
Principal Consultant
Regulatory Insight, Inc.
13 Red Fox Lane
Littleton, CO 80127

Re: K051940
Trade/Device Name: CM 3910 Rotating Double Scheimpflug Camera
Regulation Number: 21 CFR 886.1850
Regulation Name: Anterior Eye-Segment Analysis Device
Regulatory Class: Class II
Product Code: MXK
Dated: July 15, 2005
Received: July 20, 2005

Dear Mr. Walls:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, reading "David M. Whipple". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: CM 3910 Rotating Double Scheimpflug Camera

Indications for Use: The CM3910 is a device intended to take images of the anterior segment of the eye which includes the cornea, iris, pupil, anterior chamber and lens, to evaluate and analyse

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- Anterior chamber (size, volume and angle)
- Scheimpflug Image
- Position of the cornea relative to iris and lens

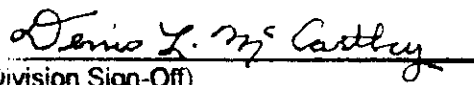
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devices

510(k) Number K051940